

What Is Claimed Is:

1. A pharmaceutical composition for moulded components comprising Eudragit 4135F present in an amount of about 15 to about 50% w/w; at least two
5 hydroxypropyl cellulose polymers, each having a differing molecular weight, present in a total amount of about 20% to about 70% w/w; a lubricant present in an amount of about 10% to about 25% w/w; and optionally a dissolution modifying excipient present in an amount of about 0% to about 70% w/w; a surfactant present in an amount of 0 to 10%, a plasticizer present in an amount of 0 to 10% w/w and/or
10 a processing agent present in an amount of 0 to about 10% w/w.
2. The composition according to Claim 1 wherein the Eudragit 4135F is present in an amount of about 15 to about 30% w/w.
- 15 3. The composition according to Claim 1 which comprises a surfactant present in an amount of less than 5% w/w.
4. The composition according to Claim 3 wherein the surfactant is sodium dodecyl sulphate or is a block copolymer of ethylene oxide and propylene oxide.
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5. The composition according to Claim 4 wherein the surfactant is sodium dodecyl sulphate is present in an amount of less than 2% w/w.
6. The composition according to Claim 4 wherein the surfactant is a block
25 copolymer of ethylene oxide and propylene oxide.
7. The composition according to Claim 1 wherein the lubricant is present in an amount of about 10 to about 30% w/w.
- 30 8. The composition according to Claim 1 wherein the lubricant is stearyl alcohol, glycerol monostearate (GMS), talc, magnesium stearate, silicon dioxide, amorphous silicic acid, or fumed silica; or a combination or mixture thereof.
9. The composition according to Claim 8 wherein the lubricant is stearyl
35 alcohol.

10. The composition according to Claim 9 wherein the stearyl alcohol is present from about 10 to about 15% w/w.

11. The composition according to Claim 1 wherein the dissolution modifying excipient is sodium starch glycollate, croscarmellose sodium, crospovidone (cross-linked polyvinyl pyrrolidone), copovidone, polyvinyl pyrrolidone copovidone, ethyl cellulose, cellulose acetate phthalate; a third hydroxypropyl cellulose polymer, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, xylitol, mannitol, lactose, starch, or sodium chloride, or a combination or mixture thereof.

12. The composition according to Claim 1 wherein the dissolution modifying excipient is sodium starch glycollate, croscarmellose sodium, crospovidone (cross-linked polyvinyl pyrrolidone), copovidone, polyvinyl pyrrolidone copovidone; or a combination or mixture thereof.

13. The composition according to Claim 1 wherein the dissolution modifying excipient is ethyl cellulose, cellulose acetate phthalate, hydroxypropylmethyl cellulose, hydroxypropylmethyl cellulose phthalate, xylitol, mannitol, lactose, starch, sodium chloride, or a combination or mixture thereof.

14. The composition according to Claim 1 wherein the dissolution modifying excipient is present in an amount of about 5 to about 15% w/w.

15. The composition according to Claim 1 wherein the plasticizer is triethyl citrate (TEC), tributyl citrate, acetyl triethyl citrate (ATEC), acetyl tributyl citrate (ATBC), dibutyl phthalate, dibutyl sebacate (DBS), diethyl phthalate, vinyl pyrrolidone glycol triacetate, polyethylene glycol, polyoxyethylene sorbitan monolaurate, propylene glycol, castor oil; or a combination or mixture thereof.

16. The composition according to Claim 1 wherein the processing agent is talc.

17. The composition according to Claim 16 wherein the processing agent is present in an amount of about 1 to about 5 % w/w.

18. The composition according to Claim 1 which further comprises an absorption enhancer.

19. The composition according to Claim 18 wherein the absorption enhancer is chitosan, lecithin, lectin, a sucrose fatty acid ester, Vitamin E-TPGS; or a combination or mixture thereof.
- 5 20. The composition according to Claim 1 wherein the Eudragit 4135F is present in an amount of about 15 to 25% w/w, the lubricant is stearyl alcohol, the dissolution modifying excipient is sodium starch glycolate, and the surfactant is sodium dodecyl sulfate or a block copolymer of ethylene oxide and propylene oxide.
- 10 21. The composition according to Claim 1 wherein the at least two HPC polymers have a resulting molecular weight of about 30,000 to about 370,000.
22. The composition according to Claim 1 wherein the at least two HPC polymers have a resulting molecular weight of about 50,000 to about 170,000.
- 15 23. The composition according to Claim 1 wherein the at least two HPC polymers have a resulting molecular weight of about 80,000 to about 140,000.
24. The composition according to Claim 1 wherein the at least two
20 hydroxypropyl cellulose polymers are independently selected from Klucel EF, Klucel E, Klucel EXF, Klucel JF, Klucel LF, Klucel GF, Nisso HPC-L and Nisso HPC-M.
25. The composition according to Claim 1 wherein the at least two
25 hydroxypropyl cellulose polymers are Klucel EF and Klucel JF.
26. The composition according to Claim 1 wherein the at least two hydroxypropyl cellulose polymers are Klucel JF and Klucel GF.
- 30 27. The composition according to Claim 1 wherein the at least two hydroxypropyl cellulose polymers are Klucel EF and Klucel GF.
28. The composition according to Claim 1 or 24 wherein the at least two hydroxypropyl cellulose polymers are present in equal w/w % amounts of each
35 component.
29. The composition according to Claim 1 or 24 wherein the at least two

hydroxypropyl cellulose polymers are present in an amount of about 32% w/w of each polymer.

30. The composition according to Claim 1 or 24 herein the dissolution
5 modifying excipient also includes a wicking agent.

31. The composition according to Claim 30 wherein the wicking agent is lactose.

32. The pharmaceutical composition for molded capsule shells comprising:

10	Component	-----%w/w-----		
		<u>A</u>	<u>B</u>	<u>C</u>
	Eudragit 4135F	24.0	24.0	24.0
	Stearyl alcohol	12.0	12.0	12.0
	Klucel EF	30.0	30.0	0.0
15	Klucel JF	30.0	0.0	30.0
	Klucel GF	0.0	30.0	30.0
	sodium starch glycollate:			
		2.0	2.0	2.0
	sodium dodecyl sulfate			
20		1.0	1.0	1.0
	polyoxypropylene-polyoxyethylene block copolymers			
		<u>1.0</u>	<u>1.0</u>	<u>1.0</u>
		100	100	100

33. A pharmaceutical composition for molded capsule shells comprising:

	Component	-----% w/w-----		
		<u>A</u>	<u>B</u>	<u>C</u>
5	Eudragit 4135F	24.0	29.0	21.0
	Stearyl alcohol	12.0	12.0	12.0
	Klucel EF	32.0	25.0	32.0
	Klucel JF	32.0	30.0	32.0
10	sodium starch glycollate:			
		0.0	2.0	2.0
	sodium dodecyl sulfate			
		0.0	1.0	0.0
	polyoxypropylene-polyoxyethylene block copolymers			
15		<u>0.0</u>	<u>1.0</u>	<u>1.0</u>
		100	100	100

34. An injection molded capsule shell, linker or spacer having a composition as defined in any one of Claims 1 to 33.

35. A multicomponent injection molded capsule shell, linker or spacer having a composition as defined in any one of Claims 1 to 33

36. A welded multicomponent injection molded capsule shell, linker or spacer having a composition as defined in any one of Claims 1 to 33.

37. A multi-component pharmaceutical dosage form which comprises a plurality of sub-units, each sub-unit being selected from

a) a drug substance-containing capsule compartment which is soluble or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the capsule compartment, and

b) a solid matrix comprising Eudragit 4135F present in an amount of about 15 to 25% w/w, at least two hydroxypropyl cellulose polymers, each having a differing molecular weight being present in a total amount of about 30% to about 64% w/w, and containing a drug substance, the polymer being soluble, dispersible or disintegrable in a patient's gastro-intestinal environment for release of the drug substance contained in the solid matrix, and in which, at least prior to administration

to a patient, the sub-units are welded together in an assembled dosage form.

38. A multi-component pharmaceutical dosage form according to Claim 37, in which at least one of the sub-units is a solid matrix comprising as
5 hydroxypropylcellulose polymers, Klucel EF and Klucel JF, each present in an amount of about 30 to 32% w/w.

39. A multi-component pharmaceutical dosage form according to Claim 37, in which at least one of the sub-units is a solid matrix comprising as
10 hydroxypropylcellulose polymers, Klucel JF and Klucel GF, each present in an amount of about 30 to 32% w/w.

40. A multi-component pharmaceutical dosage form according to Claim 37, in which at least one of the sub-units is a solid matrix comprising as
15 hydroxypropylcellulose polymers, Klucel EF and Klucel GF, each present in an amount of about 30 to 32% w/w.

41. A multi-component pharmaceutical dosage form according to Claim 37, in which the solid matrix also comprises a lubricant present in an amount of about 10
20 to about 25% w/w.

42. A dosage form according to Claim 37, in which at least one of the sub-units is a drug substance-containing capsule compartment having a wall with a thickness in the range of about 0.3 – 0.8 mm.

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43. A dosage form according to Claim 42, in which at least one of the sub-units is a substantially immediate release sub-unit.